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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,577	02/12/2001	Irene E. Kochevar	10284-018001	9723

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EXAMINER

BARRETT, THOMAS C

ART UNIT PAPER NUMBER

3738

DATE MAILED: 06/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary

Application No.

09/781,577

Applicant(s)

KOCHEVAR ET AL.

Examiner

Thomas C. Barrett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-26 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-20, 23-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

REQUEST FOR CONTINUED EXAMINATION

The request filed on May 19, 2005 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/781,577 is acceptable and a RCE has been established. An action on the RCE follows.

Response to Arguments

Applicant's arguments filed November 17, 2004 have been fully considered but they are not persuasive. As noted in the advisory action:

The Applicant argues "In the Khadem Declaration, an exogenous protein substrate concentration of at least 1% is described as a critical ingredient of photoactivable compositions for use in tissue bonding. Thus, as stated by Dr. Hamblin and as supported by the documentary evidence provided herein, the description in Column 7 lines 18-30 and Table 2 of Khadem lack enablement for the claimed methods and the remaining disclosure in Khadem does not fill the gap." However, as noted in the prior action "The declaration states, "it is my opinion, as one of ordinary skill in the art, who has read the Khadem patent, that portions of the patent other than column 7 lines 18-30 cannot be relied upon for additional instruction because they are solely intended for methods that require application of an exogenous substrate" . Therefore the declaration admits the "four sentences" are directed to methods that do not require application of exogenous substrates." and therefore the prior art is enabled.

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Furthermore, regarding the Khadem declaration, column 7 lines 18-30 of the prior cited Khadem reference also discloses "Such methods utilize the peptides or proteins located naturally within the tissue area as in situ protein containing compositions." Contrary to the Applicant's argument Khadem never declares the protein used to be exogenous protein as defined in the present application. Therefore the Khadem declaration does not show the Khadem patent to lack enablement.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation wherein "the second tissue is derived from amniotic membrane" was not described in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14, 17-20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Khadem et al. (5,552,452) as cited in applicant's IDS. Khadem et al. discloses a method for adhering tissue comprising: contacting a tissue with a photosensitizer, creating a tissue-photosensitizer mixture, applying electromagnetic energy without more than a 1 degree rise in temperature (col. 3, line 67- col. 4, line 3), which therefore doesn't produce "substantial" thermal damage , and creating a tissue seal without contacting the tissue with an exogenous cross-linkable substrate (col. 7, lines 18-30). The method may comprise the use of Rose Bengal and energy applied at 600-670 nm (Table 1) or a thiazine (col. 4, line 64- col. 5, line 3), and can be used for refractive surgery (col. 8, lines 3-8). The methods can be used on humans and in vivo or ex vivo (col. 15, lines 39-47).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-16 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khadem et al. (5,552,452). Khadem et al. discloses a method for adhering tissue comprising: contacting a tissue with a photosensitizer, creating a tissue-

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photosensitizer mixture, applying electromagnetic energy without more than a 1 degree rise in temperature however Khadem et al. fails to disclose specific W/cm, and J/cm ranges. MPEP 2144.05 states:

II. OPTIMIZATION OF RANGES

A. Optimization Within Prior Art Conditions or Through Routine Experimentation

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

The general conditions of the claims are disclosed in Khadem et al. Khadem et al. discloses adhering tissue using a laser at wavelengths greater than 488 nm and a photosensitizer under conditions that minimize tissue damage (col. 2, lines 55-67). Lasers are well known in the art to have controllable energy doses and irradiances, such as the commercial ones admitted to by the Applicant (pp 15-16). The optimum ranges of energy doses and irradiances can easily be found through routine experimentation. It would have been obvious to one of ordinary skill in the art to combine the teaching of routine experimentation to determine the optimum ranges of energy doses and irradiances, to a method for adhering tissue as per Khadem et al., in order to minimize tissue damage.

In addition, Khadem discloses, "Likewise, the application of the electromagnetic radiation will also be adapted to suit the particular circumstances of operation. It is generally envisioned that the time for performing a tissue closure procedure in

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accordance herewith will be less than five minutes in total." The optimum length of application of the electromagnetic radiation can easily be found through routine experimentation (col. 7, lines 31-45). It would have been obvious to one of ordinary skill in the art to combine the teaching of routine experimentation to determine the optimum length of application of the electromagnetic radiation, to a method for adhering tissue as per Khadem et al., in order to ensure tissue closure.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Thomas Barrett", with a stylized flourish at the end.

Thomas Barrett
Examiner
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